

## Drive and Leverage Innovation for Pharma

### A Report on the 2019 ISPE Europe Annual Conference



by Sabine Paris, PhD

The European Annual Conference of the International Society of Pharmaceutical Engineering (ISPE) attracted over 700 participants to Dublin from 1<sup>st</sup> to 3<sup>rd</sup> April 2019. The main topic was "Drive and Leverage Innovation for Pharma". The Executive Forum focused on the industrial digitisation as a key enabler to drive innovation. Driving continuous improvement in a digital age needs a number of pre-requisites and face new challenges and opportunities.

In today's leading article I have summed up the most decisive trends and future challenges as seen by the top-class lecturers in the executive plenary and keynote sessions.

I have also published this text (and much more) in my live coverage of the conference at [LinkedIn](#) (#gmppublishing).

***„Digital technology and data are transforming everything we do and our digital transformation journey has begun.“***

The first speaker was **Pam Cheng** from AstraZeneca who enthusiastically talked about digital technology and data. Regarding pharmaceutical manufacturing Pam highlighted:

- 3D printing of tablets in the future
- Predictive and prescriptive analytics
- Digital twins: get to a robust process much faster, accelerate design of new drug's process
- Voice directed technology: changeover with headset, operator will be guided through the procedure, advantages: clear instructions, less errors
- Connected drones: to inspect the facilities
- Data science: big data on the shop floor – how do we connect all data?

Another key question of the first afternoon was: **Can we predict future quality?**

Pam reported on predictive maintenance that AstraZeneca introduced for a packaging line in Sweden. Line failures can be predicted – you can intervene before things fail.

*„New half-live of a skill is 5 years!“*

Pam recommended to look at the digital things that surround you. That means continuous learning is the most important factor.

Last but not least, people are one of the key success drivers for the factory of the future!



### Quo vadis with operations?

**Thomas Wozniewski**, as the global head of operations for all technologies and factories from the new Takeda/Shire operations, gave his perspective on global relevant success factors for manufacturing and quality.

He referenced a new living stemcell product, Alofisel<sup>®</sup>, that is challenging for many reasons, e.g. shelf life, storage temperatures, batch size, timing of production (directly before surgery). Tests on sterility are quick tests, or the release is conditional before the results of the test are available.

There are digital supply chain solutions for Alofisel<sup>®</sup>: a nurse can go in with an app and book a production slot. You get even real time feedback from the hospital about the condition of the patient.

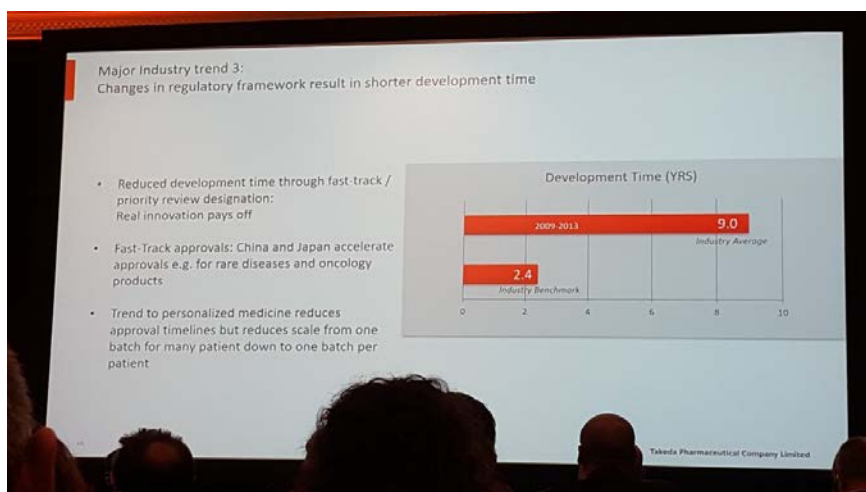
### „There are 4 major industry trends.“

Trend 1: Changing technologies

Trend 2: Drug product & device combination

Trend 3: Changes in regulatory framework result in shorter development time: fast track approvals

Trend 4: Environmental sustainability matters!



Big data and digitalisation will have great influence on global manufacturing and supply.

- Big data analytics across the global manufacturing and supply network
- Data analytics capabilities
- Supply chain visualization (identification with barcode)
- Lead site concept: artificial intelligence in automatic line clearance
- Virtual reality training
- Digital best practice sharing (drone inspections, digital LOTpaper, ...)
- 3D printing of spare parts

### Developing next generation biologics

**Brendan O'Callaghan** from Sanofi started the keynote sessions with his lecture on **Developing Next Generation Biologics**. Brendan introduces Sanofi's strategy for future manufacturing that includes:

- Multi-targeting molecules
- Inhouse developing model (formerly nearly only external partner for biologics)
- Investing in internal capacity & capabilities
- Expanding capacity through strategic partnerships (selected partner, gives flexibility, opportunity to scale-up)
- Preparing the future through innovative technology platforms (next generation of biologics, integrated continuous manufacturing, with small reactors: reduction in footprint – fully paperless)

A new US site that realizes integrated continuous biomanufacturing has the following advantages:

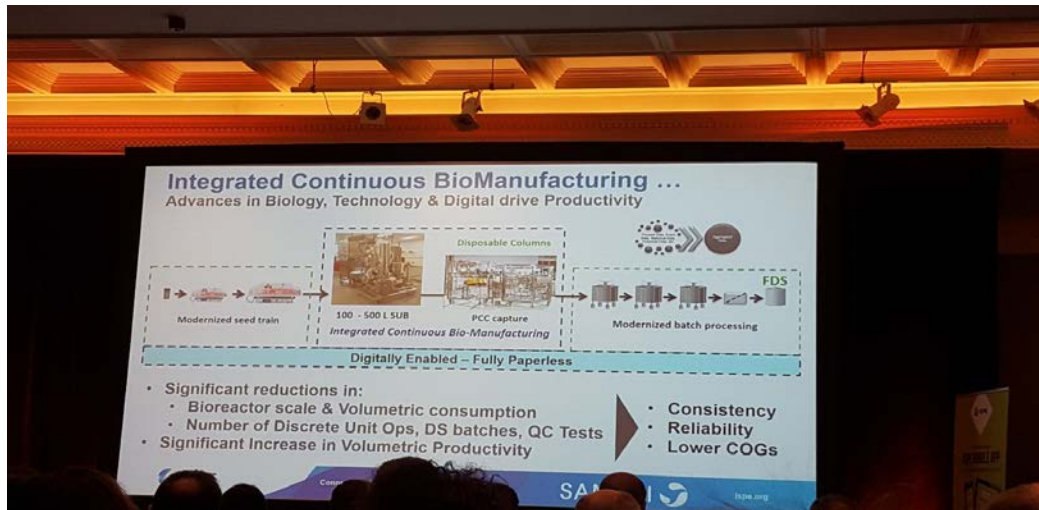
- Footprint reduction 50 %
- Bioreactor size moving from 4 x 2000 l to 2 x 100 l
- Unit operation reduction 50-60 %
- Reduction of cleaning through single use
- Rapid product changes possible
- Increasing productivity
- Better consistency
- Better reliability
- Lower COG (Cost of Goods)

Digital technology is one prerequisite for a factory of the future. Brendan mentioned in this context:

- Digital connectivity: real time understanding of the needs (manufacturing linked to sales office)
- Operators get information in real time (data streaming), you can monitor the process in real time

- Connected equipment – predictive maintenance
- Smart quality: at line, in line sampling and testing, work cross tests, capability to the shop floor to make their own quality test
- Right time release: automated verification, quality testing
- Digital twin technology: also used for training of the staff before the plant opens, and also used to simulate changes

With its new facility, Sanofi has already realized the factory of the future!



### Sources:

2019 ISPE Europe Annual Conference:

Pam P. Cheng, Executive Vice President – Global Operations & IT, AstraZeneca: Global Success Factor: Innovation and Digitisation

Thomas Wozniowski, Global Manufacturing & Supply Officer, Takeda: The Transformation of Global Manufacturing and Supply at Takeda

Brendan D. O'Callaghan, Senior Vice President & Global Head Biologics Platform, Sanofi: Developing Next Generation Biologics

### Author:

**Sabine Paris, PhD**

Editorial Department

Maas & Peither AG – GMP Publishing

E-Mail: [sabine.paris@gmp-publishing.com](mailto:sabine.paris@gmp-publishing.com)